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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known

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|-------------------------------|---------------------------------|
| Application Number | 10/607,479 |
| Filing Date | June 26, 2003 |
| First Named Inventor | Lawrence S. Young et al. |
| Art Unit | 4845 1632 |
| Examiner Name | Not Yet Assigned |
| Attorney Docket Number | HARR0032-101 |

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|-------|---|----|---|------------------------|
| Sheet | 1 | of | 5 | Attorney Docket Number |
|-------|---|----|---|------------------------|

U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|-----------------------|---|--------------------------------|---|---|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ^a |
| | | Country Code ² - Number ³ - Kind Code ³ (if known) | | | | |
| SDP | ✓ AB | EP 0 939 122 A1 | 09/01/1999 | Universiteit Utrecht | | Yes |
| | ✓ AC | WO 91/17773 | 11/28/1991 | Birstiel et al. | | Yes ✓ |
| | ✓ AD | WO 91/18088 | 11/28/1991 | Chatterjee and Wong | | Yes |
| | ✓ AE | WO 93/08288 | 04/29/1993 | Anlezark et al. | | Yes |
| | ✓ AF | WO 93/18759 | 09/30/1993 | Smith and Woo | | Yes |
| | ✓ AG | WO 95/02698 | 01/26/1995 | Jessee | | Yes |
| | ✓ AH | WO 95/30020 | 11/09/1995 | Midoux et al. | | Yes - |
| | / AI | WO 96/41606 | 12/27/1996 | Thatcher et al. | | Yes |
| | ✓ AJ | WO 98/07876 | 02/26/1998 | Antoniou and Grosveld | | Yes |

Abstract only

Abstract only

**Examiner
Signature**

Scott J. Priebe

Date Considered

6/30/05

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PTO/SB/08a (08-03)



PTO/SB/08b(08-03)

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**INFORMATION DISCLOSURE
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Sheet

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of

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|------------------------|--------------------------|
| Application Number | 10/607,479 |
| Filing Date | June 26, 2003 |
| First Named Inventor | Lawrence S. Young et al. |
| Art Unit | 1645 1632 |
| Examiner Name | Not Yet Assigned |
| Attorney Docket Number | HARR0032-101 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| SDP | AN | Anderson, W.F., "Human gene therapy," <i>Nature</i> , 392 (Supp):25-30, April 30, 1998 | |
| | AO | Calos, M., "The potential of extrachromosomal replicating vectors for gene therapy," <i>TIG</i> , 12(11):463-466, 1996 | |
| | AP | Chowdhury, J.R. et al., "Long-Term Improvement of Hypercholesterolemia After ex Vivo Gene Therapy in LDLR-Deficient Rabbits," <i>Science</i> , 254:1802-1805, December 20, 1991 | |
| | AQ | Cotton, M. et al., "Receptor-Mediated Transport of DNA into Eukaryotic Cells," <i>Meth. Enzymol.</i> , 217:618-644, 1992 | |
| | AR | Eastman, Q. and Grosschedl, R., "Regulation of LEF-1/TCF transcription factors by Wnt and other signals," <i>Current Opin. Cell Biol.</i> , 11:233-240, 1999 | |
| | AS | Emerson, S.G., "Ex Vivo Expansion of Hematopoietic Precursors, Progenitors, and Stem Cells: The Next Generation of Cellular Therapeutics," <i>Blood</i> , 87(8):3082-3088, April 15, 1996 | |
| | AT | Fallaux, F.J. et al., "New Helper Cells and Matched Early Region 1-Deleted Adenovirus Vectors Prevent Generation of Replication-Competent Adenoviruses," <i>Human Gene Ther.</i> , 9:1909-1917, September 1, 1998 | |
| | AU | Flotte, T.R. et al., "Stable in vivo expression of the cystic fibrosis transmembrane conductance regulator with an adeno-associated virus vector," <i>Proc. Natl. Acad. Sci. USA</i> , 90:10613-10617, November, 1993 | |
| | AV | He, T.C. et al., "Identification of c-MYC as a Target of the APC Pathway," <i>Science</i> , 281:1509-1512, September 4, 1998 | |
| | AW | Hengge, U.R. et al., "Cytokine gene expression in epidermis with biological effects following injection of naked DNA," <i>Nature Genetics</i> , 10:161-166, 1995 | |
| | AX | Hickman, M.A. et al., "Gene Expression Following Direction Injection of DNA into Liver," <i>Human Gene Ther.</i> , 5:1477-1483, December, 1994 | |
| | AY | Hitt, M.M. et al., "Human Adenovirus Vectors for Gene Transfer into Mammalian Cells," <i>Advances in Pharmacology</i> , 40:137-206, 1997 | |
| | AZ | Keown, W.A. et al., "Methods for Introducing DNA into Mammalian Cells," <i>Methods Enzymol.</i> , 185:527-537, 1990 | |

Examiner
Signature

Scott D. Pinke

Date
Considered

6/30/05

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 4

of

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Complete if Known

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|------------------------|--------------------------|
| Application Number | 10/607,479 |
| Filing Date | June 26, 2003 |
| First Named Inventor | Lawrence S. Young et al. |
| Art Unit | 2545-1632 |
| Examiner Name | Not Yet Assigned |
| Attorney Docket Number | HARR0032-101 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| SDP | BA | Korinek, V. et al., "Constitutive Transcriptional Activation by a β -catenin-Tcf Complex in APC ⁺ Colon Carcinoma," <i>Science</i> , 275:1784-1787, March 21, 1997 | |
| | BB | Kucherlapati, R. and Skoultschi, A.I., "Introduction of Purified Genes into Mammalian Cells," <i>Crit. Rev. Biochem.</i> , 16(4):349-379, 1984 | |
| | BC | Lickert, H. et al., "Wnt/ β -catenin signaling regulates the expression of the homeobox gene <i>Cdx1</i> in embryonic intestine," <i>Development</i> , 127:3805-3813, 2000 | |
| | BD | Love, J.J. et al., "Structural basis for DNA bending by the architectural transcription factor LEF-1," <i>Nature</i> , 376:791-795, August 31, 1995 | |
| | BE | Mack, K.D. et al., "Cationic Lipid Enhances In Vitro Receptor-Mediated Transfection," <i>The American Journal of the Medical Sciences</i> , 307(2):138-143, 1994 | |
| | BF | Meyer, K.B. et al., "Intratracheal gene delivery to the mouse airway: characterization of plasmid DNA expression and pharmacokinetics," <i>Gene Therapy</i> , 2:450-460, 1995 | |
| | BG | Morin, P.J. et al., "Activation of β -Catenin-Tcf Signaling in Colon Cancer by Mutations in β -Catenin or APC," <i>Science</i> , 275:1787-1790, March 21, 1997 | |
| | BH | Miller, J.L. et al., "Recombinant adeno-associated virus (rAAV)-mediated expression of a human γ -globin gene in human progenitor-derived erythroid cells," <i>Proc. Natl. Acad. Sci. USA</i> , 91:10183-10187, October, 1994 | |
| | BI | Phillip, R. et al., "Efficient and Sustained Gene Expression in Primary T Lymphocytes and Primary and Cultured Tumor Cells Mediated by Adeno-Associated Virus Plasmid DNA Complexed to Cationic Liposomes," <i>Mol. Cell. Biol.</i> , 14(4):2411-2418, April 1994 | |
| | BJ | Plank, C. et al., "The Influenced of Endosome-disruptive Peptides on Gene Transfer Using Synthetic Virus-like Gene Transfer Systems," <i>J. Biol. Chem.</i> , 269(17):12918-12924, April 29, 1994 | |
| | BK | Russell, D.W. et al., "Adeno-associated virus vectors preferentially transduced cells in S phase," <i>Proc. Natl. Acad. Sci. USA</i> , 91:8915-8919, September, 1994 | |
| | BL | Shtutman, M. et al., "The cyclin D1 gene is a target of the β -catenin/LEF-1 pathway," <i>Proc. Natl. Acad. Sci. USA</i> , 96:5522-5527, May, 1999 | |
| | BM | Sikes, M.L. et al., "In Vivo Transfer into Rabbit Thyroid Follicular Cells by Direct DNA Injection," <i>Human Gene Ther.</i> , 5:837-844, 1994 | |

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| Examiner Signature | <i>Scott D. Pinko</i> | Date Considered | 6/30/05 |
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Sheet 5 of 5

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| Application Number | 10/607,479 |
| Filing Date | June 26, 2003 |
| First Named Inventor | Lawrence S. Young et al. |
| Art Unit | 1845 / 632 |
| Examiner Name | Not Yet Assigned |
| Attorney Docket Number | HARR0032-101 |

| NON PATENT LITERATURE DOCUMENTS | | | |
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| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| SDP | BN | Tetsu, O. and McCormick, F., "β-Catenin regulates expression of cyclin D1 in colon carcinoma cells," <i>Nature</i> , 398:422-426, April 1, 1999 | |
| | BO | Trubetsky, V.S. et al., "Use of N-Terminal Modified Poly(L-lysine)-Antibody Conjugate as a Carrier for Targeted Gene Delivery in Mouse Lung Endothelial Cells," <i>Bioconjugate Chem.</i> , 3:323-327, 1992 | |
| | BP | Ustav, M. and Stenlund, A., "Transient replication of BPV-1 requires two viral polypeptides encoded by the E1 and E2 open reading frames," <i>The EMBO J.</i> , 10(2):449-457, 1991 | |
| | BQ | van de Wetering, M. et al., "Identification and cloning of TCF-1, a T lymphocyte-specific transcription factor containing a sequence-specific HMG box," <i>The EMBO J.</i> , 10(1):123-132, 1991 | |
| | BR | Vile, R.G. and Hart, I.R., "In Vitro and in Vivo Targeting of Gene Expression to Melanoma Cells," <i>Cancer Res.</i> , 53:962-967, 1993 | |
| | BS | Walsh, C.E. et al., "Regulated high level expression of a human γ-globin gene introduced into erythroid cells by an adeno-associated virus vector," <i>Proc. Natl. Acad. Sci. USA</i> , 89:7257-7261, August, 1992 | |
| | BT | Watanabe, M. et al., "Nucleotide sequence of <i>Salmonella typhimurium</i> nitroreductase gene," <i>Nucleic Acids Res.</i> , 18(4):1059, 1990 | |
| | BU | Wilson, J.M. et al., "Ex Vivo Gene Therapy of Familial Hypercholesterolemia," <i>Human Gene Ther.</i> , 3:179-222, 1992 | |
| | BV | Wilson, J.M. et al., "Hepatocyte-directed Gene Transfer in vivo Leads to Transient Improvement of Hypercholesterolemia in Low Density Lipoprotein Receptor-deficient Rabbits," <i>J. Biol. Chem.</i> , 267(2):963-967, January 15, 1992 | |
| | BW | Wolff, J.A. et al., "Direct Gene Transfer into Mouse Muscle in Vivo," <i>Science</i> , 247:1465-1468, March 23, 1990 | |
| | BX | Wu and Wu, "Receptor-mediated Gene Delivery and Expression in Vivo," <i>J. Biol. Chem.</i> , 263(29):14621-14624, October 15, 1988 | |
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Examiner
Signature

Scott D. Pink

Date
Considered

6/30/05

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